

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0975983	(X3) Date Survey Completed 05/01/2023
Name of Provider or Supplier Thompson Oncology Group	Street Address, City, State 9711 Sherrill Blvd, Knoxville, TN	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Proficiency Testing Policy, proficiency testing records, documented corrective action and staff interview, the laboratory failed to follow the proficiency testing policy for corrective action for ungraded proficiency testing results in 2022. The findings include: 1. Review of the laboratory's Proficiency Testing policy under the section for "Result review of proficiency testing" revealed the following statements: "5. Results not graded document review of the following by completing an investigation or corrective action form" "d. Specimen determined to be unsatisfactory after contacting Proficiency Testing Service (perform alternate assessment)". 2. Review of the laboratory's proficiency testing records revealed 2022 hematology Event 3 scores for all analytes as "0". 3. Review of the laboratory's documented corrective action failed to include performance of alternate assessment for ungraded proficiency testing results due to unsatisfactory proficiency testing samples. 4. Interview with the technical consultant on 05.01.2023 at approximately 10:00 a.m. confirmed the laboratory failed to follow the proficiency testing policy for performance of alternate assessment as it relates to ungraded proficiency testing when proficiency testing samples were determined to be unsatisfactory after contacting the Proficiency Testing service for hematology 2022 Event 3.</p>